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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/933,569	08/20/2001	Thomas Wild	9793/97	5757

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EXAMINER

DAVIS, DEBORAH A

ART UNIT	PAPER NUMBER
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1641

DATE MAILED: 06/17/2003

15

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/933,569

Applicant(s)

WILD ET AL.

Examiner

Deborah A Davis

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 April 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 11-15, 17-23 and 25-26 is/are pending in the application.
- 4a) Of the above claim(s) 27-32 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 11-15, 17-23, 25 and 26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 15. 6) ☐ Other: _____

DETAILED ACTION

1. Applicant's response to the Office Action mailed December 13, 2002 (Paper #14) is acknowledged. Claims 1-10, 16 and 24 are cancelled. Claims 27-32 are drawn to non-elected subject matter. Claims 11-15, 17-23 and 25-26 are under consideration for examination.

Information Disclosure Statement

2. The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609 A(1) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 11-15 and 17-19, 21-23, 25-26 are rejected under 35 U.S.C. 102(b) as being by Hevey et al (USP#4,228,237).

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Hevey et al teaches methods for the detection and determination of ligands utilizing a biotin/avidin system. Claims 11-14 and 17-19 are anticipated by the reference in teaching several embodiments of an assay and methods that determine the presence and amount of a ligand. One embodiment teaches an enzyme (2nd hapten) coupled to avidin (binding partner); avidin is bound to a biotin (1st hapten) labeled reagent that comprise of a specific binding substance (analyte specific component) for the determination of a ligand. The specific binding substance (analyte specific component) is specific for binding the ligand in the assay (see summary, lines 1-50). The ligand in this embodiment exhibits binding specificity to the specific binding substance (analyte specific component) and the exclusion of other substance in the assay (col. 4, lines 31-36). Hevey et al teaches that when the ligand is a hapten, a specific binding substance utilized to detect the hapten is an antibody produced when the hapten, bound to an antigenic carrier is introduced into a sample (col. 4, lines 61-65). Hevey et al teaches that during the binding steps, the reagents may be incubated individually or in particular sequence, as taught in claims 11, 17-18 (col. 2, lines 58-62). The reaction is measured by the activity of the enzyme labeled avidin (col. 3, lines 64-68 & col. 4, lines 1-5). Examples of solid carriers used in this invention range from microtiter plates to nylon beads (col. 5, lines 32-41). HRP labeled avidin is pre-reacted with biotin labeled antibody, which is added to the insoluble phase after the antigen has been incubated as taught in claim 26 (col. 9, lines 29-35). In a non-competitive binding process, the insoluble phase may be incubated with the reagents together in the presence of one another, as taught in claim 25 (col. 2, lines 58-62).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 13 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hevey et al (USP#4,228,237) in view of Huber et al (USP# 5,219,764).

The teachings of Hevey et al are set forth above and differ from the instant claims in not teaching that the second hapten or hapten like molecule is identical to or an analogue of the first hapten or hapten-like molecule.

However, Huber et al teaches hapten-biotin conjugates and their use. Huber et al teaches that haptens occur in small amounts therefore detection methods are based on immunoassay that can be classified into homogeneous and heterogeneous (col. 1, lines 1-34). It was also established that by using the hapten-biotin conjugates improved sensitivity and the rate of the reaction is increased (col. 2, lines 50-54).

It would have been obvious to one of ordinary skill in the art to modify the reference of Hevey et al to include the use of identical haptens or its analog in an assay system as taught by Huber et al because haptens improve sensitivity and the rate of reaction is increased (col. 2, lines 50-54). Further, identical haptens or its analogs have same or similar molecular weights or biological structure and contain the same or

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similar binding properties. Further, it is well within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of an obvious choice. Absent evidence to the contrary the selection of known haptens in the assay taught by the prior art is merely a design choice routinely modified in these methods.

Response to Arguments

7. Applicant's arguments filed April 14, 2003 have been fully considered but they are not persuasive. Applicant's argument that the Hevey et al reference does not meet every element in particular, in particular element (c) in independent claim 11, which comprise of an assay component that includes a binding partner that binds the 1st and 2nd hapten or hapten-like molecule without reacting with the analyte is considered but not found persuasive because Hevel et al teaches variations of the assay embodiments. For example, one embodiment teaches an enzyme (2nd hapten) coupled to avidin (wherein avidin is the binding partner); avidin (binding partner) is bound to a biotin (1st hapten) labeled reagent that comprise of a specific binding substance (analyte specific component) for the determination of a ligand. The specific binding substance (analyte specific component) is specific for binding the ligand in the assay (see summary, lines 1-50). The ligand in this embodiment only show binding specificity to the specific binding substance and excludes binding of other substances in the assay which includes the 1st and 2nd hapten (col. 4, lines 31-36). Therefore, the Hevey et al reference anticipates the instant claims and rejection maintained and made final.

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8. Applicant's argument that the Hevey et al and Huber et al references alone or in combination does not teach the assay component (c) and the elements of the assay is not found persuasive for the same reasons aforementioned in response to the Hevey et al arguments provided above. Therefore, it is concluded that the instant claims are obvious over the Hevey et al in view of Huber et al references and the rejection is maintained and made final.

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

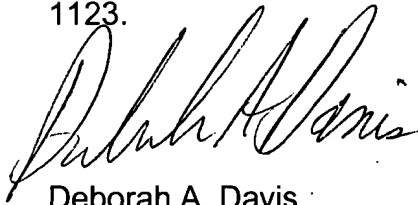
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah A Davis whose telephone number is (703) 308-4427. The examiner can normally be reached on 8-5 Monday thru Friday.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Davis Deborah can be reached on (703) 308-4427. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1123.



Deborah A. Davis
CM1, 7D16
June 4, 2003



LONG V. LE
SUPERVISORY PATENT EXAMINER
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06/16/03